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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,990

07/14/2003

Scott Cunningham

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UNITED STATES SURGICAL,
A DIVISION OF TYCO HEALTHCARE GROUP LP
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EXAMINER

POUS, NATALIE R

ART UNIT

PAPER NUMBER

3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,990	Applicant(s) CUNNINGHAM ET AL.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/10/07, 11/20/03, 10/16/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to the claim have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 12-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sardelis (US 5730732) in view of Wong (US 5030228), further in view of Allen (US 5403344), and further in view of Saito (US 5820609).

Sardelis teaches a surgical needle comprising the following features:

- an elongated substantially linear needle body defining a longitudinal y-axis (50)
- the needle body including a central shaft portion (60)
- a first suture end portion for attachment to a suture (80)
- a second needled end portion for penetrating tissue (70)
- the needled end portion (70) having three sides which intersect to define three cutting edges (90)
- and terminating at a needle point (70)
- the needled end portion further defining an enlarged transition portion (Line 7-7) adjacent the central shaft section with an x-dimension (height) at least substantially equal to a corresponding x-dimension of the central shaft (line 8-8).
- the enlarged transition portion defines an x- dimension x_1 (Line 7-7) greater than a corresponding x-dimension x_1 (Line 8-8) of the central shaft portion (Fig. 6).
- the enlarged transition portion defines a z- dimension (width) at least substantially equal to a corresponding z-dimension of the central shaft (90, Fig. 5).
- the enlarged transition portion defines a z- dimension greater than a corresponding z-dimension of the central shaft portion (90, Fig. 5).
- The x-dimension and z-dimensions of the enlarged transition portion is defined between adjacent cutting edges (90, fig. 7)

- The central shaft portion defines a distal transition portion adjacent the needled end portion, the distal shaft portion defining a cross section of general triangular character (fig. 8)
- Wherein the needle body is adapted to assume a curved configuration (it is noted that based on the material and structure of the device, it is capable of being formed into a curved configuration)

Sardelis fails to disclose wherein each side includes a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance to the respective side.

Wong teaches a surgical needle wherein sides include a pair of planar surface portions (14, 22) arranged in oblique relation and intersecting along a median plane (18) bisecting a respective side to define a general concave appearance to the respective side (Column 3, proximate lines 32-35), wherein the angle between the planar surfaces is about 170 degrees (Column 3, proximate lines 64-66), and two of the cutting edges intersect at the needle point (P) and define an angle of about 22° to about 25° (Column 3, proximate lines 47-48) in order to provide a needle with improved penetration and smaller wound opening that is easy to form (Column 2, proximate lines 7-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the needle sides of Sardelis with a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance to the respective side in order to provide a needle with improved penetration and smaller wound opening that is easy to form.

The combination of Sardelis and Wong fails to teach wherein each side has a generally concave appearance. Allen teaches a surgical needle wherein each side includes a pair of planar surfaces (25, 26) arranged in an oblique relation in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area (Column 3, proximate lines 55-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the surgical needle of the combination of Sardelis and Wong with planar surfaces arranged in an oblique relation on each side as taught by Allen in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area.

The combination of Sardelis, Wong and Allen fails to teach wherein the needle point is displaced a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension x_t of the enlarged transition portion. Saito teaches a needle for insertion into a patient, wherein the needle tip is both offset from the longitudinal axis of the needle and the lowest surface of the needle in order to decrease the amount of pain felt by the patient during insertion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Sardelis, Wong and Allen as taught by Saito in order to decrease the amount of pain felt by the patient during insertion.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sardelis, Wong, Allen and Saito as applied to claims 1 and 8 above, and

further in view of Smith et al. (US 5797961). The combination of Sardelis, Wong, Allen and Saito teaches all limitations of preceding dependent claims 1 and 8 as previously described, but fails to teach wherein the distal shaft portion surfaces are interconnected by rounded surfaces. Smith teaches a cutting edge needle wherein the distal shaft surfaces (41) are interconnected by rounded surfaces (fig. 6) in order to provide the cross-section of central section 40 such that a conventional needle-grasper can sufficiently grasp and effectively maintain the needle 5 in a fixed position as the needle 5 penetrates body tissue without the needle slipping between the jaws of the needle grasper. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Sardelis, Wong, Allen and Saito with distal shaft portion surfaces interconnected by rounded surfaces as taught by Smith in order to provide the cross-section of central section 40 such that a conventional needle-grasper can sufficiently grasp and effectively maintain the needle 5 in a fixed position as the needle 5 penetrates body tissue without the needle slipping between the jaws of the needle grasper.

Claims 22, 23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sardelis, Wong, Allen and Saito and further in view of Smith (US 4513747). The combination of Sardelis, Wong, Allen and Saito teach all limitations of preceding dependent claims 1 and 12, but fails to teach wherein each cutting edge is substantially linear, and wherein at least one side of the needled end portion forms an angle α with the longitudinal y-axis, the angle α being between about 2° and 10° . Smith teaches a surgical needle, wherein each cutting edge is substantially

linear (fig. 1), and wherein at least one side of the needled end portion forms an angle α with the longitudinal y-axis, the angle α being between about 2° and 10° (Column 5, proximate lines 4-10) in order to provide for ease of passage of the needle through the tissue (Column 5, proximate lines 45-50), Due to lack of criticality in the specification, linear cutting edges were shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a circular one on the device. Therefore, it would have been obvious to make the cutting edges because it is capable of working equally as well as a circular-shaped foreign body locator, and further providing this configuration is well known in the art, as described by Smith.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
5/2/07



(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

5/07/07